

CERTIFICATE OF FACSIMILE

I hereby certify that this paper is being transmitted via facsimile to: Mail Stop RCE; Commissioner for Patents; P.O. Box 1450; Alexandria, VA 22313-1450 at facsimile number **571-273-8300** on May 16, 2007.

*Sornie S. Dell*

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Sabine Stumvoll et al : Paper No.:  
Serial No.: 10/027,625 : Group Art Unit: 1644  
Filing Date: December 21, 2001 : Examiner: Nolan, Patrick J

For: Use of a Pure Allergen Component

DECLARATION UNDER 37 CFR 1.132

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

DR. PAOLO COLOMBO declares as follows:

1. He is a coinventor of and is familiar with the present U.S. Patent Application Serial No. 10/027,625 filed December 21, 2001 and entitled "Use of a Pure Allergen Component" and he is familiar with the Official Action dated November 16, 2006 issued in this application and with Duro et al, *FEBS Letters*, 399 (1996), 295-298 cited in the Official Action, of which he is an author.

2. He is currently employed by Istituto di Biomedicina e di Immunologia Molecolare, Palermo, Italy, and holds the position of Group Leader. Since prior to 1996, he has studied and researched allergy diagnosis and treatment.

3. Based on his experience in the art of allergy diagnosis and treatment, he provides the following observations regarding the teachings of Duro et al to one of ordinary skill in the art:

The paper by Duro et al. (*FEBS Letter* 1996) reported the isolation of a major allergen of the *Parietaria judaica* pollen (Par j2). In this paper, the Authors demonstrated that the Par j2 protein is a major allergen since a large number of *Parietaria* allergic patients present IgE towards this molecule.

4. Having reviewed the Duro et al reference, he does not find any disclosure therein which, in his opinion, would suggest to one of ordinary skill in the art a method for serological diagnosis for an individual known to be allergic of an actual sensitizing allergen source from among a variety of possible allergen sources containing cross-reactive proteins or epitopes with improved accuracy. In particular, the present U.S. Application Serial No. 10/027,625 is directed to methods which provide with the possibility to use this single component, Par j2 to identify genuine sensitized *Parietaria* allergic patients. The Duro et al paper does not disclose or suggest that the Par j2 allergen is not cross-reactive with allergen components from other allergen sources. Thus, the Duro et al paper does not teach or suggest using Par j2 or any other purified allergen component in methods for diagnosis of the actual sensitizing source from a variety of possible allergen sources as the present application claims. In fact, a later paper by Stumvoll et al. (*JACI* 2003) showed that the *Parietaria* pollen contains independent families of allergens with different immunological relevance. In particular, Stumvoll were able to show the presence of cross-reactive and species-specific allergens in *Parietaria* pollen. The Par j2 allergen belongs to the latter family and neither this discovery nor a method employing it were disclosed or suggested by the Duro et al paper.

5. He hereby declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and

further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Paolo Colombo

DR. PAOLO COLOMBO

04/05/2007

Date